Technical Specification

Sectra MicroDose Mammography L30
Software 8.3

SECTRA

Technical Specification - Sectra MicroDose Mammography L30 Software 8.3

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1. Introduction

1.1 Purpose

The purpose of this document is to supply the reader with technical data for the Sectra MicroDose Mammography™ L30 modality.

1.2 Scope

The information in this document applies to the Sectra MicroDose Mammography L30 modality.

1.3 Intended readers

This document is intended for persons requiring technical data for the Sectra MicroDose Mammography L30 modality. For full understanding of some of the chapters the intended reader is required the knowledge level of an engineer.

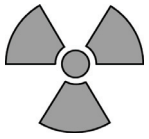
1.4 Language

This document was originally written in English (UK).
In case of uncertainties regarding the content in translated versions of this document, it is the English (UK) version (document number: 1007996) that is to be regarded as the original.

1.5 Chapter overview

Chapter 1 – Introduction to this document
Chapter 2 – Technical specification of the mammography stand, standard configuration (for screening)

1.6 Symbols Used in This Document

Warning!	*Warning is used when severe danger for patient, personnel or system exists.*
Caution!	*Caution is used when danger for patient, personnel or system exists.*
Notice	*Notice is used to underline information of importance.*
Exposure 	*The exposure symbol is used when an exposure is made.*

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1.7 References

[1] European Guidelines for Quality Assurance in Breast Screening and Diagnosis, 4th Edition, 2006.

[2] S. Eklund, A. Thilander, W. Leitz, S. Mattson, "The impact of anatomic variations on absorbed radiation doses in mammography," Radiat. Prot. Dosim. 49, 167 -17 0 (1993).

[3] K. C. Young, M. L. Ramsdale, and F. Bignell, "Review of dosimetric methods for mammography in the UK breast screening programme," Radiat. Prot. Dosim. 80, 183-186 (1998).

[4] B. Heddson, K. Rönnow, M. Olsson, D. P. Miller, "Digital vs. Screen-Film Mammography: A Retrospective Comparison in a Population-Based Screening Program", accepted for publication in the European Journal of Radiology.

[5] Validation of mobile mammography vehicles, the Sectra Mamea AB document DOC-JLUG-7C3CU8.

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2. Technical specification of the mammography stand

Sectra Imtec AB reserves the right to make necessary changes and amendments to the specification below.

2.1 Model and manufacturer

Model information	
Model name	Sectra MicroDose Mammography L30
Manufacturer	Sectra Imtec AB Teknikringen 20 SE 583 30 Linköping Sweden

2.2 Regulatory requirements

European requirements	
CE labelling	Class IIb. ”Council Directive 93/42/EEC” concerning medical devices. The product is labelled with the CE mark with identification number 0434 which authenticates the compliance with the directive.
National and international standards	
The system is tested according to the following standards.	IEC 60601-1: 1988 and A1+A2[1] IEC 60601-1-2:2001 IEC 60601-1-3:1994 IEC 60601-1-4:1996 IEC 60601-2-28:1993 IEC 60601-2-32:1994[2] IEC 60601-2-45:2001
Equipment classification (according to IEC 60601-1 §5): - Type of protection against electrical shock: - Degree of protection against electrical shock: - Degree of protection against harmful ingress of water: - Mode of operation:	 Class I equipment Type B Ordinary equipment Continuous operation with intermittent loading, permanent installation.
Non-sterilizable equipment	
Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or with nitrous oxide.	

[1] The protective earth impedance between acquisition workstation and incoming protective earth is about 130 mΩ, which exceeds the prescribed maximum level of 100mΩ. The acquisition workstation is connected to floating voltage and the impedance between acquisition workstation and fixed mains switch is about 135 mΩ (prescribed maximum level 200 mΩ).

[2] Note: Sectra MicroDose Mammography L30 is equipped with auto positioning (rotation) for the C-arm, which is a violation towards the standard IEC 60601-2-32; 22.4.1. The system is however provided with collision protection means and meets the requirement for CE-marking.

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2.3 Electromagnetic compatibility

Caution! *The use of accessories, transducers and cables other than those specified by Sectra or sold by Sectra as replacement parts, may result in increased emissions or decreased immunity of the L30 system.*

Electromagnetic emissions		
Model L30 is intended for use in the electromagnetic environment specified below. The customer or the user of model L30 should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The L30 uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	Model L30 is classified as professional equipment and has an active power consumption > 1000W at normal load. According to standards the limits are not applicable.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity		
Model L30 is intended for use in the electromagnetic environment specified below. The customer or the user of model L30 should assure that it is used in such an environment.		
Immunity test	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	Up to 6 kV contact discharge and 8 kV air discharge	
Electrical fast transient / burst IEC 61000-4-4	2 kV for power supply lines	
Surge IEC 61000-4-5	1 kV differential mode, 2 kV common mode	

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Electromagnetic immunity		
		Portable and mobile RF communications equipment should be used no closer to any part of the L30, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted disturbances induced by RF fields IEC 61000-4-6. (V1)	V1 =10 V and 80% AM modulation with 1 kHz at frequency range 0,15 – 80 MHz	Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$
Radiated disturbances induced by RF fields IEC 61000-4-3 (E1)	10 V/m and 80% AM modulation with 1 kHz at frequency range 80-2500 MHz E1 = 10 V/m	$d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz P = maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer d = recommended separation distance in metres (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[3] should be less than the compliance level in each frequency range.[4] Interference may occur in the vicinity of equipment marked with the following symbol:
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95% dip for 10 ms. 60% dip for 100 ms. 30% dip for 500 ms.	Power loss may result in unwanted power off of model L30. In such cases re-calibration of the system is necessary.

[3] Note: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the L30 is used exceeds the applicable RF compliance level above, the L30 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the L30.

[4] Note: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

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Electromagnetic immunity		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	N/A	The L30 is not sensitive for power frequency magnetic fields.

Electromagnetic immunity

Recommended separation distances between portable and mobile RF communications equipment and the Sectra MicroDose Mammography L30 modality.

The Sectra MicroDose Mammography L30 modality is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Sectra MicroDose Mammography L30 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sectra MicroDose Mammography L30 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter P (W)	Separation distance according to frequency of transmitter d (m)		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0,01	0,035	0,035	0,07
0,1	0,11	0,11	0,22
1	0,35	0,35	0,7
10	1,11	1,11	2,21
100	3,5	3,5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

2.4 Installation

Installation information	
Installation and service	Only personnel certified by Sectra may perform installation and service of the equipment.
Radiation protection	Installation must be done in accordance with local radiation protection regulations.

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2.5 Electrical data

Electrical Requirements	
Input mains connection	380/400/415 VAC 50Hz Three phase (protective earth + 3 phases)
Fuse	32 A
The electrical connection of the equipment shall be permanent	
Fixed mains switch	External, isolated 100 A. Approved according to IEC 328 and IEC 447. The fixed mains switch shall cut supply current by one single action, and shall be possible to lock in OFF mode. The fixed mains switch shall be a mechanical switch, and shall be placed in immediate proximity to the side cabinet. Sectra recommends that, if the side cabinet is not placed in the examination room, an additional switch is placed in the examination room.
Input impedance	Maximum 0.4Ω
Peak power	12 kVA Average power at normal duty cycle 2.5 kVA
Duty cycle	A 7 second exposure / minute at 35 kV, 200 mA. (Average during one hour.)
Power supply cord	Required cross sectional area: 10 mm² The power supply cord shall comply with IEC 60245 or IEC 60227. Stranded conductors shall not be soldered. The cord delivered with the system is approximately 5 m (from the cable outlet at the backside of the side cabinet). The diameter is approximately 20 mm.
Input mains connection, network isolation, galvanic isolation	
Network isolation unit, when using network connection Alternative 3 or Alternative 4 (see 2.15).	
Input mains connection	100-240 V AC, 50-60Hz, single phase
Galvanic isolation	It is important that the system (except for mains supply) is galvanic isolated from the surrounding. For example water connections, the floor in the examination room and when the system is bolted to the floor of a trailer chassis.

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2.6 Environment

Operating environment - Mammography stand & Acquisition workstation	
Temperature	+10° C to +30° C (at maximum workflow).
Temperature change	3° C / hour
Humidity	30% to 75 % (non condensing)
Atmospheric pressure	700 hPa to 1060 hPa
Mechanically active substances like dust and sand	Similar levels to a normal office environment, i.e. without special precautions to minimize the presence of sand or dust, but is not situated in proximity to sources of sand or dust.
Operating environment - Side cabinet	
Temperature	+10° C to +30° C (maximum work flow).
Temperature change	3° C / hour
Humidity	30% to 75 % (non condensing)
Atmospheric pressure	700 hPa to 1060 hPa
Mechanically active substances like dust and sand	Similar levels to a normal office environment, i.e. without special precautions to minimize the presence of sand or dust, but is not situated in proximity to sources of sand or dust.
Mobile Installations	
Vehicle requirements	See [5]
Controlled area	
Access to the equipment must be restricted in accordance with local regulations.	
Transport and storage	
Temperature	+5° C to +30° C -10° C to +50° C, less than 1 day
Humidity	10% to 75% (non condensing) 95% max, less than 2 weeks
Atmospheric pressure	500 hPa to 1060 hPa
Mechanically active substances like dust and sand	Similar levels to a normal indoor environment, i.e. without special precautions to minimize the presence of sand or dust, but is not situated in proximity to sources of sand or dust.
Fire-extinguisher	
Type	Powder

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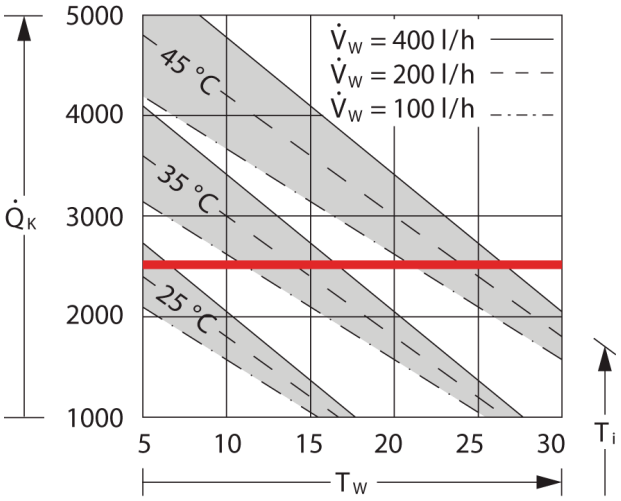
2.7 Heat dissipation and cooling

Main cabinet with AW table	
Heat dissipation (total) for both air and water cooled option.	0.7 kW (maximum work flow) 0.4 kW (stand-by mode)
Side cabinet: **Air cooling (standard configuration)**	
Heat dissipation specification (total)	2.5 kW (maximum work flow) 1.5 kW (stand-by mode)
Side cabinet : **Water cooling (municipal cooling network)**	
Capacity of water cooling	2.5 kW (maximum work flow) 1.5 kW (stand-by mode)
Water cooling (municipal cooling network)	Performance diagram  $\dot{Q}_K$ Cooling output (W) T_W Water inlet temperature T_i Enclosure internal temperature $\dot{V}_W$ Water volume flow **Example:** If the enclosure temperature is 25°C, the cooling capacity of the water cooler will be 2.5 kW if the water flow is 350 litres/hour, at 100 kPa (nominal) and the incoming water temperature is approximately 6°C. Maximum water flow: 400 litres/hour Water pressure: 1-10 bar (100 – 1000 kPa)
Chiller fittings	The chiller has G 1/2" (R15) fittings.

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2.8 Measures and weights

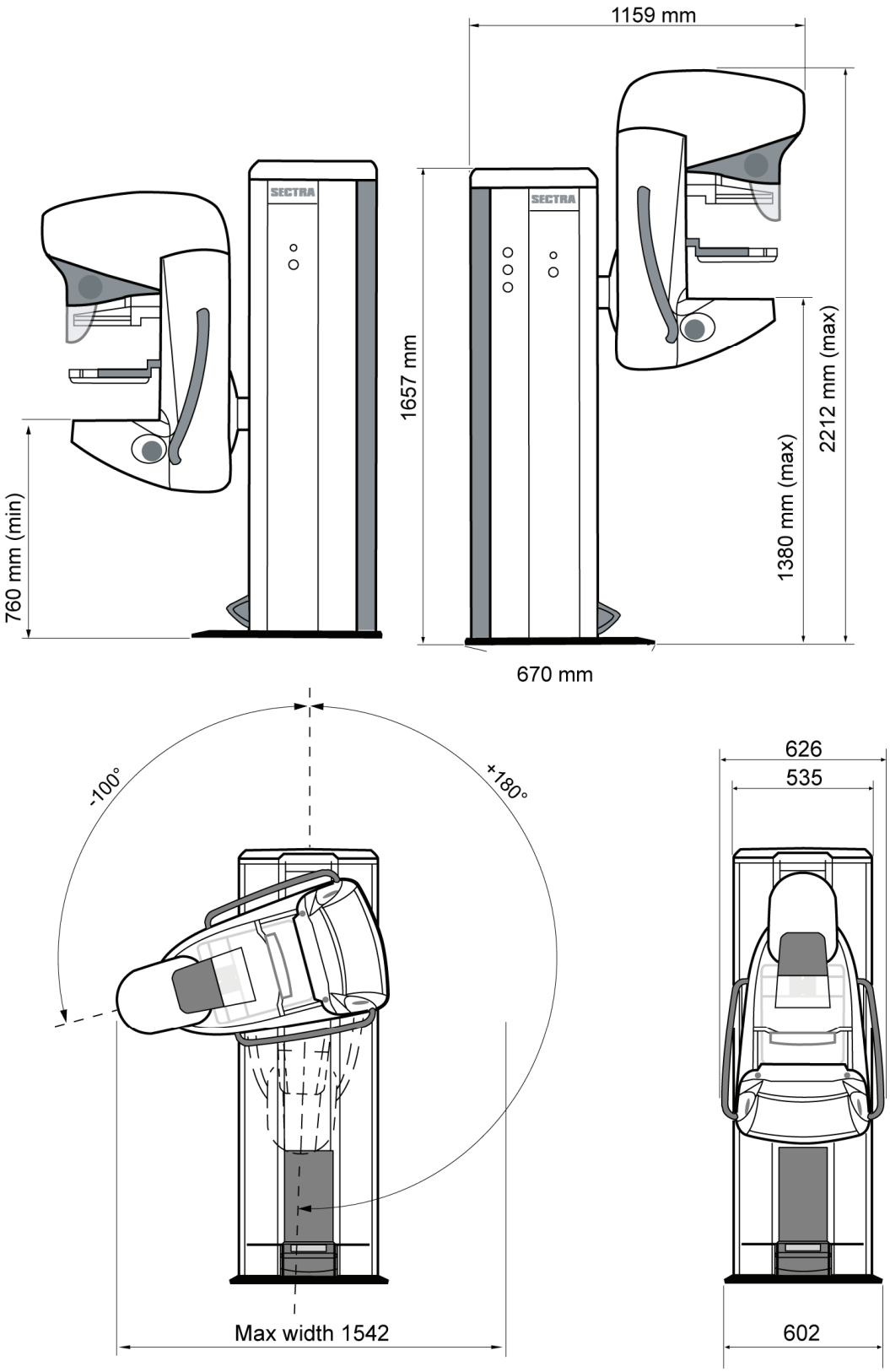

Figure 1 Measures of Mammography stand.

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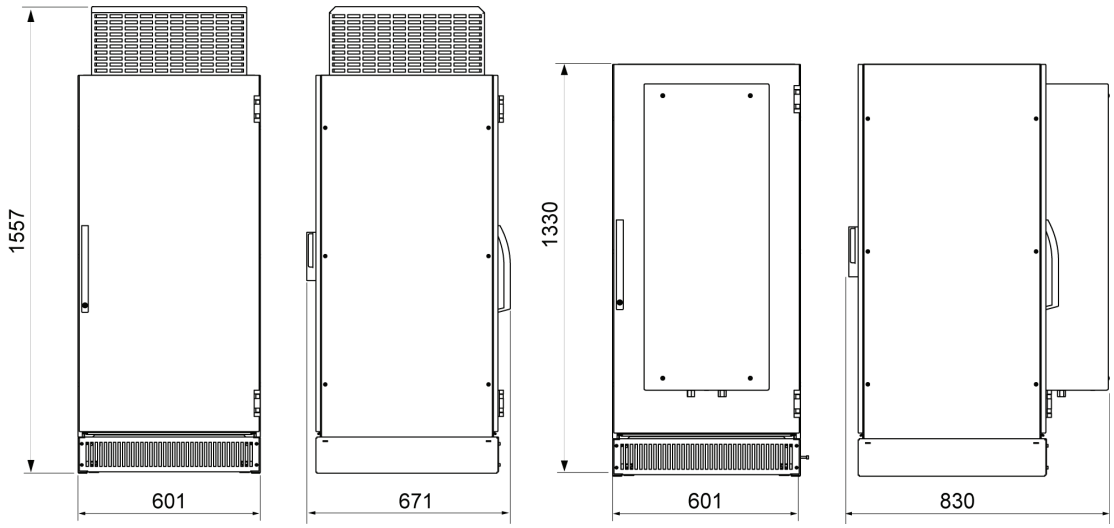

Figure 2 Measures of Side cabinet.
Left: Air cooling (standard) Right: Water cooling (optional)

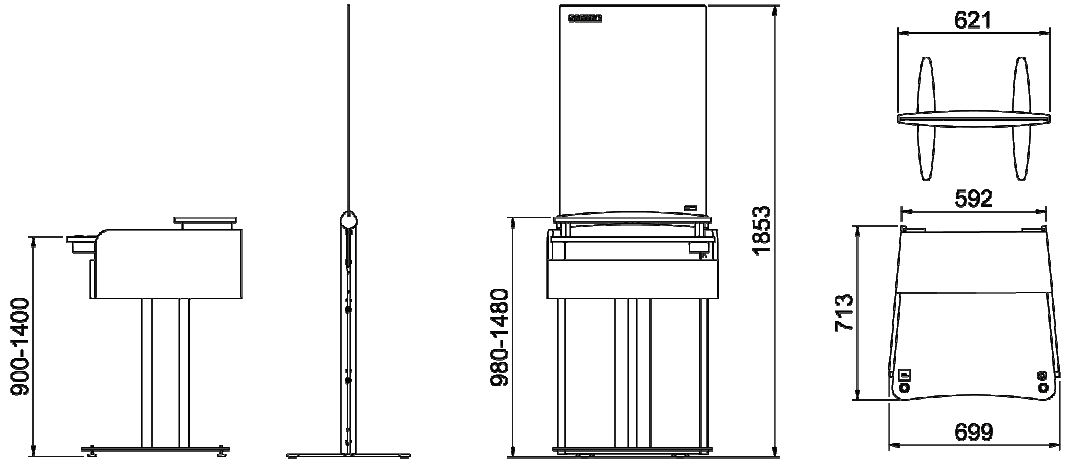

Figure 3 Measures of Acquisition Workstation table and radiation protection shield.

Mammography stand	
Measures	See Figure 1
Weight	260 kg
Measures with packaging	800x1800 mm, height 1600 mm
Weight with packaging	320 kg
Side cabinet	
Measures with standard cooling	See Figure 2, left
Measures with optional cooling	See Figure 2, right
Weight with standard cooling	260 kg
Weight with optional cooling	260 kg
Measures with packaging	800x1200 mm, height 1600 mm
Weight with packaging	300 kg

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C-arm	
Height (from floor to patient support)	760 – 1380 mm
Speed of rotational motion	10°/second
Speed of vertical movement	50 mm/s
Rotation - standard configuration	-100° to + 180°
Automatic positioning (including isocentric C-arm rotation)	Dx CC, Sin CC, Dx MLO, Sin MLO, Dx LM, Sin LM
Limitation of C-arm movement (vertical movement and rotation)	At compression force greater than 50 N, C-arm movement is not possible.
Collision protection	Yes
Accuracy of display of rotation angle	± 1°
SID (Source Image Distance)	660 mm
Source to patient support distance	640 mm
Missed tissue at chest wall	5 mm
Radiation protection shield	
Measures	See Figure 3
Weight (lead glass shield)	29.5 kg
Acquisition Workstation table	
Measures	See Figure 3
Weight	75 kg
Network isolation	
Network isolation unit, when using network connection Alternative 3 or Alternative 4 (see 2.15). To be mounted close to mains electrical outlet.	
Measures	Height: 25 mm Width: 105 mm Depth: 95 mm
Weight	0.27 kg
Placement	
Maximum distance between mammography stand and Side Cabinet (from cable outlet to cable outlet).	Cable length 6 m.
Maximum distance between mammography stand and Acquisition workstation table (from cable outlet to cable outlet).	Cable length 9.5 m (can be adjusted to 19.5 m at request)
Required free space at both sides of the C-arm rotated 90° (either to the left or to the right).	600 mm
Required free space around the side cabinet	200 mm (on all sides, for air circulation)
The side cabinet must be placed at the same level as the mammography stand, i.e. it cannot be Placed e.g. one floor upstairs.	
A designated significant zone of occupancy for the operator is required during exposing. The size of this area shall be at least 60x60x200 cm.	
Cable routing	
Total diameter of hoses and cables including connectors between side cabinet and main cabinet.	Minimum diameter 75 mm.
Total diameter of cables including connectors between main cabinet and AW-table.	Minimum diameter 60 mm.

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2.9 Compression

Compression	
Motion	0-150 mm
Maximum compression height at exposure	100 mm (for standard compression paddle)
Accuracy of display of breast thickness	± 2 mm
First stop limit for compression	12 daN (configurable 0-20 daN)
Compression force	0 – 200 N
Compression paddles	- Standard - High edge - Spot (optional) - Low Spot (optional) - Small (optional) - Medium (optional) - Matrix (optional) - Window (optional)
Release of compression	- Pedals that control the movement of the compression paddle. - Automatic release after exposure. (Unless the "Keep compression" option has been chosen.) - Release of compression force in case of power loss. - Release of compression force if the emergency stop is activated.
Accuracy of display of compression force.	± 20 N

2.10 X-ray source

X-ray tube	
Maximum tube voltage	40 kVp
Maximum power to the anode	6.8 kW (at 38 kVp, 180 mA)
Maximum tube current at maximum tube voltage	170 mA at 40 kVp
Maximum tube current	180 mA
Maximum tube voltage at maximum tube current	38 kVp at 180 mA
Maximum allowed energy deposition to the anode per hour	5220 kJ/h (130 500 mAs/h at 40 kVp)
Anode material	Tungsten
Anode disc size	∅ 102 mm
Anode rotation speed	10800 RPM
Focal spot size - standard configuration	0.3 according to IEC 60336
Anode angle	16° (the tube is mounted with a tilt of 7° in a way that 23° angle is achieved relative the reference axis)
Anode heat capacity	445kJ (600 kHU)
Maximum heat radiated from the anode	1.5 kW (121.5 kHU/min)
Cooling	Oil-air exchanger (fan)
Accompanying documentation	
Data sheet X-ray tube	Technical Data sheet for Varian RAD-70-type tube

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Service manual X-ray tube	X-ray tube Service Manual – Varian #14423
Service report X-ray tube	Mammography Tube Service Report – Varian #4989

2.11 X-ray radiation and X-ray protection

Relation between mAs_{eff} and conventional mAs

- mAs is tube current × exposure time of x-ray tube (not to be confused with the exposure time for a point in the image field).
- Effective mAs (mAs_{eff}) is the mAs corrected for the fraction of open area in the collimator in relation to the total scan length, i.e. this is the mAs that a point in the image plane experiences during a scan.

X-ray radiation

Inherent filtration from the X-ray tube	0.76 mm Be
Added filter 1004803	0.40 mm Al
Total filtration (including collimator cradle 1004897)	0.46 mm Al equivalent at 30 kVp
Half-value layer after filtering without compression paddle (a 3 mm compression paddle increases HVL with 0.12 mm Al at 30 kVp)	26 kVp, 0.27 mm Al 32 kVp, 0.34 mm Al 38 kVp, 0.41 mm Al (values in-between can be linearly interpolated)
Air kerma typical values 45 mm above the patient support and 60 mm from the edge of the patient support, compression paddle present.	0.09 mGy/mAs_{eff} at 26 kVp 0.15 mGy/ mAs_{eff} at 32 kVp 0.22 mGy/ mAs_{eff} at 38 kVp (values in-between can be linearly interpolated)
Tube voltage, tube current and exposure time providing maximum radiation leakage	40 kVp, 170 mA, 15 s

Dose levels

Breast thickness	C100 dose setting	C120 dose setting	Acceptable level [1]	Achievable level [1]
3 cm	0.34 – 0.41	0.60 – 0.74	<1.2	<0.9
5 cm	0.40 – 0.49	0.68 – 0.84	<2.3	<1.8
8 cm	0.9 – 1.1	1.2 – 1.4	<5.7	<4.6
Population-averaged	0.5 – 0.6	0.8 – 1.0	n/a	n/a

Table 1: Measured AGD (mGy) and limiting values from European guidelines [1]. Confidence intervals are 2 standard deviations. Also included are population-based dose values, i.e. dose averaged over a measured breast thickness distribution. Conversion factors were taken from *)

*) Further factors for the estimation of mean glandular dose using the United Kingdom, European and IAEA breast dosimetry protocols, D R Dance, K C Young and R E van Engen, Phys Med Biol, 54 (2009), 4361-4372.

C100	The C100 dose configuration corresponds to a set of target image quality figures that meet the so-called Acceptable limiting values in the European Guidelines [1].
C120	This dose configuration corresponds to a set of image quality figures that provide 20% higher SDNR (*a.k.a.* CNR) than the C100 setting. This is equivalent to being able to see 20% thinner objects of the same size.
C200	This dose level can only be used with the spot compression paddle and small image field. SDNR is roughly doubled and the dose four times higher compared to C100.

Radiation reference axis

The radiation reference axis is pointed towards the edge of the digital detector closest to the chest wall. The radiation is collimated in a way that no radiation comes outside the edge of the patient support that is close to the chest wall.

Patient support attenuation

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Patient support	0.05 mm Al equivalence at 30kVp (W anode and HVL 0.3 mm Al)
X-ray radiation protection	
Protective lead glass	0.5 mm Pb equivalent at 55-120kVp

2.11.1 Designated zone of occupancy

A designated significant zone of occupancy for the operator is required during exposing. The size shall be at least 60x60x200 cm (W x D x H).

Personnel working with the equipment should occupy this zone of occupancy during exposure. Figure 4 defines the zone of occupancy.

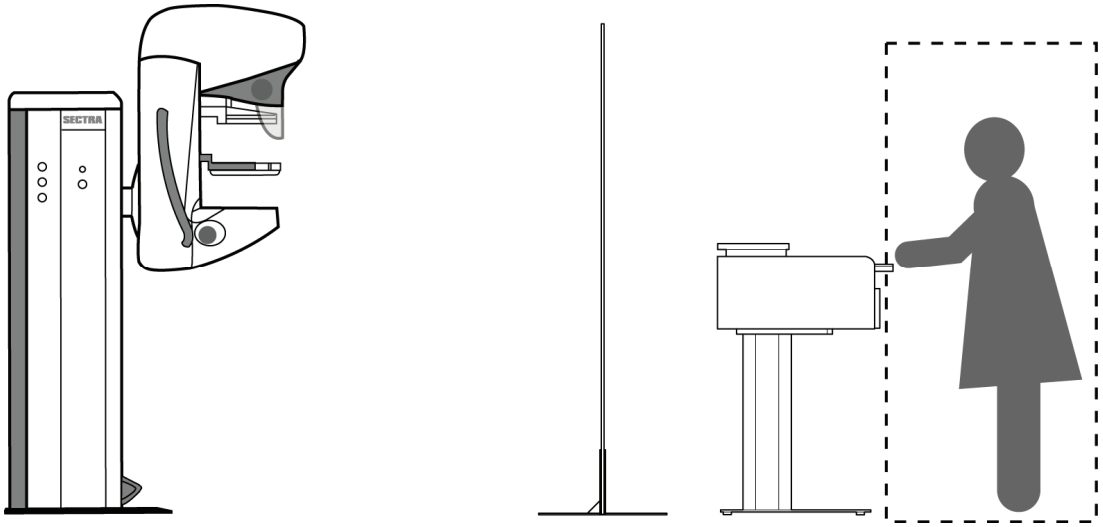

Figure 4 The zone of occupancy.

The radiation protection shield should be positioned in accordance with Figure 4 to minimize the radiation exposure to the operator.

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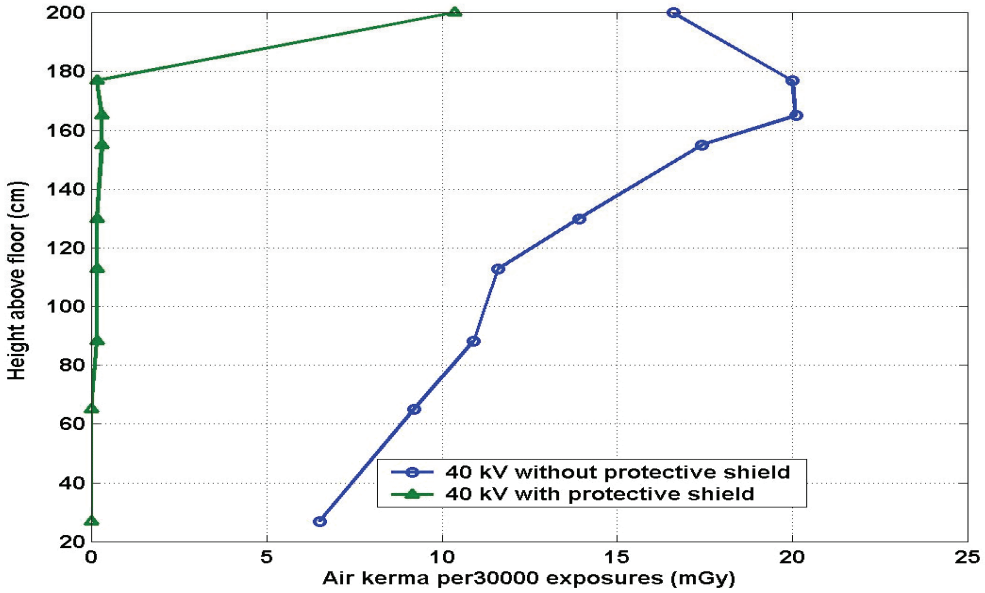

Figure 5 *The figure illustrates the intensity profile of the scattered radiation as function of height above the floor, with and without the protective lead glass. The data in the figure is normalised to 30,000 exposures. The measurements were performed 120 cm from the scattering volume. 5x30x30 cm3 PMMA in the radiation field was used as scattering volume. The exposure parameters were 40 kVp, 170 mA and 7 s (40 kVp, 10.4 mAs).*

2.12 Generator

High voltage generator	
Power	9 kW
kV range	20 – 40 kVp The system is typically calibrated for only 5 different kVp values.
mA range	50 – 210 mA
Maximum mAs	4000 mAs
Ripple	Max. 1%

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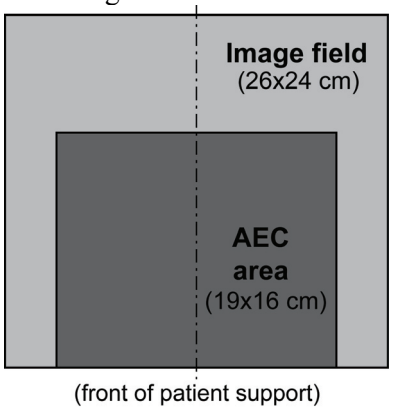
2.13 Exposure

<table>
<tr><th colspan="2">Exposure control</th></tr>
<tr><td>Exposure settings</td><td>SmartAEC™ , Automatic or Manual, where SmartAEC and Automatic are different types of automatic exposure modes.</td></tr>
<tr><td>Accuracy of kV indicator</td><td>± 2.0 %</td></tr>
<tr><td>Accuracy of mAs indicator</td><td>± 10 %</td></tr>
<tr><td>Termination of exposure</td><td>The X-ray exposure is terminated when any of the following limits are reached:
- the end of the image field (primary)
- timeout of scan-time + safety margin (secondary)</td></tr>
<tr><th colspan="2">Automatic exposure control</th></tr>
<tr><td>kVp-range</td><td>26 – 38 kVp</td></tr>
<tr><td>mAs-range</td><td>Range of effective mAs:
<table>
<tr><th></th><th>Standard image field</th><th>Spot image field</th></tr>
<tr><td>26 kVp</td><td>5.7 – 23</td><td>12 – 55</td></tr>
<tr><td>29 kVp</td><td>6.2 – 24</td><td>13 – 60</td></tr>
<tr><td>32 kVp</td><td>6.5 – 26</td><td>13 – 63</td></tr>
<tr><td>35 kVp</td><td>6.5 – 26</td><td>13 – 63</td></tr>
<tr><td>38 kVp</td><td>6.5 – 26</td><td>13 – 63</td></tr>
</table></td></tr>
<tr><td>SmartAEC™</td><td>SmartAEC exposure mode continuously adjusts the exposure, during the image scan, according to feedback from the detector.
 
</td></tr>
<tr><td>SmartAEC – acceptable objects</td><td>For SmartAEC exposure mode, the following objects may be within the AEC area:
• Breast
• Hand
• Skin markers
• Bracketing wires
• Standard compression paddle
• Medium compression paddle
• Small compression paddle
• High edge compression paddle</td></tr>
</table>

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SmartAEC– erroneous objects	For *Smart*AEC exposure mode, other objects than the above mentioned within the AEC sensor area, may cause increased patient dose. These foreign objects should be placed outside the AEC sensor area or should be exposed with Automatic or Manual exposure.
Automatic	Exposure parameters (kV and mAs) are set automatically based on measured thickness during compression.
Scanning technology	
Scan-time	4 – 16.5 s
Scatter to primary ratio	< 0.05

2.14 Detector and image parameters

Digital detector	
Detector technology	Photon Counting
Detector material	Crystalline silicon
Dynamic resolution	1 photon
Absorption efficiency	90% for 30 kVp and a 45 mm breast
Dynamic range	15 bits
Pixel size	50 µm
Nyquist frequency	10 lp/mm
Field of View (FOV)	240 mm × 260 mm (standard mode) 240 mm × 126 mm (configurable only with spot compression)
Image size (data)	~50 Mb (uncompressed, standard configuration)
Low frequency detective quantum efficiency	>0.65 at 1 mm^{-1} (measured according to the standard IEC 62220-1-2)
High frequency detective quantum efficiency	>0.24 at 4 mm^{-1} (measured according to the standard IEC 62220-1-2 and averaged from scan-direction and perpendicular direction)
Modulation transfer function	>0.45 at 4 mm^{-1} on patient support >0.47 at 4 mm^{-1} 45 mm above patient support (MTF measured 6 cm from chest wall and laterally centred, and averaged from scan-direction and perpendicular direction)

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2.15 Acquisition Workstation

Hardware	
Computer	PC
CPU	Pentium 4 / 3.2 GHz (minimum)
Storage capacity	Up to 2500 (breast) images.
Display	Standard Display: • Min 19” with 1 Mpx (1280x1024) Optional DICOM Displays: • Min 19” with 1 Mpx (1280x1024) • Min 21” with 3 Mpx (2048x1536)
Keypad with quick-keys	Yes
Keyboard	Yes
Mouse	Yes
Network connection	
Alternative 1, Gigabit fibre network	MMF fibre cable 50/125 or 62.5/125 micron, SC connectors
Alternative 2, 100 Mbps fibre network	
Alternative 3, Gigabit copper network	Category 5 cable RJ45 – RJ45 connectors
Alternative 4, 100 Mbps copper network	
Alternative 5, no network connection	Support for external disk with specification: • USB 2.0 interface • Hard disk based • No separate power supply • Minimum storage capacity 160 GB
Software	
Operating system	Microsoft Windows XP Professional
DICOM SOP Classes supported	• Verification as SCU (Service Class User) • Basic Grayscale Print Management Meta as SCU (not supported in connection alternative 5) • Modality Performed Procedure Step (MPPS) as SCU (not supported in connection alternative 5) • Digital Mammography Image Storage - For Presentation as SCU • Digital Mammography Image Storage - For Processing as SCU • Digital X-Ray Image Storage - For Presentation as SCU • Digital X-Ray Image Storage - For Processing as SCU • Modality Worklist as SCU • Storage Commitment Push Model SOP Class as SCU (not supported in connection alternative 5)

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Parameters visible in the digital image shown on the Acquisition Workstation	Always shown parameters: • Side • Projection • Image setting (e.g. ”Implant”) Other parameters are optional, but default for standard breast images are: • Patient name • Patient ID-number • kV and mAs • Patient dose (organ dose) • Compression height • Image time (exposure)

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2.16 Labels

(Serial numbers and batch numbers rendered in images are fictive.)

Labelled part	Information on label	Comment
Complete modality		Three identical labels. • One visible on the back of the main cabinet. • One visible on the outside of the side cabinet door. • An extra label is provided separately. If required by local regulations, the label is attached to the inside of the hatch of the acquisition workstation table.
Read the Manual, Electronic Waste & Electric Safety, Class B product		Two identical labels. • One visible on the back of the main cabinet. • One visible on the outside of the side cabinet door.
Acquisition workstation table (optional)		The label is provided separately. If required by local regulations, the label is attached to the front of the acquisition workstation table.
Acquisition workstation table		Label visible on top of the acquisition workstation table.

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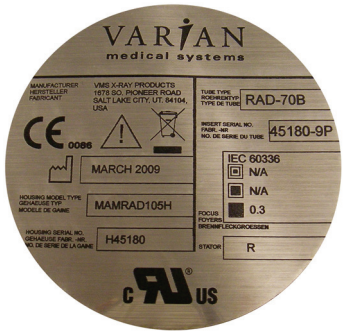
Labelled part	Information on label	Comment
X-ray tube and main cabinet (optional)		Two identical labels. • One label is attached to the X-ray tube under the C-arm covers. • An extra label is provided separately. If required by local regulations, the label is attached either to the underside of the top cover of the main cabinet or to the lower right side of the main cabinet.
Laser holder		Label placed on the laser unit intended for wire localization.
X-ray radiation shield	SECTRA Lead Equiv. 0.5 mm X-ray radiation shield Part no: 1014060	Label visible on the front side.
Filter & Collimator cradle assembly	SECTRA Al Equiv. 0.5mm Filter & Collimator cradle asm Part no: 1004807 Serial no: 10002-10	Label visible on the mounting device of the X-ray tube.
Standard compression paddle	SECTRA Std Compression Paddle Asm Part no: 1005258 Rev. X	Label visible on the side of the compression paddle.
Spot compression paddle	SECTRA Spot Compression Paddle Asm Part no: 1006738 Rev. X	Label visible on the side of the compression paddle.
Small compression paddle	SECTRA Small Compression Paddle Asm Part no: 1006741 Rev. X	Label visible on the side of the compression paddle.
Medium compression paddle	SECTRA Medium Compression Paddle Asm Part no: 1007828 Rev. X	Label visible on the side of the compression paddle.

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Labelled part	Information on label	Comment
High edge compression paddle	SECTRA High edge Compr. Paddle Asm Part no: 1007831 Rev. X	Label visible on the side of the compression paddle.
Matrix compression paddle	SECTRA Matrix Compr. Paddle Asm Part no: 1017956 Rev. X	Label visible on the side of the compression paddle.
Window compression paddle	SECTRA Window Compr. Paddle Asm Part no: 1017954 Rev. X	Label visible on the side of the compression paddle.
Low Spot compression paddle	SECTRA Low Spot Compr. Paddle Asm Part no: 1018060 Rev. X	Label visible on the side of the compression paddle.
Face protection shield	SECTRA Shield Part no: 1006467 Rev. X	Label visible on the side of the Face protection shield.
Acquisition workstation table	SECTRA Acquisition workstation table Part no: 1016465 Rev. X	Label visible on the front side of the AWP.
Pre Collimator with Cradle	SECTRA Pre Collimator w Cradle Part no: 1011510 Rev. X Serial no: 107649-10	Label visible on the side of the Collimator cradle assembly.
X-ray tube	SECTRA X-ray tube 6,7 deg asm Part no: 1012143 Rev. X Serial no: 108130-10	Label visible on the mounting device of the X-ray tube.
Laser holder	SECTRA Laser Holder Asm Part no: 1017764 Rev. X AA, 1.5 V	Label visible on the laser unit intended for wire localization.
Guidance bracket	SECTRA Guidance Bracket Asm Part no: 1017822 Rev. X	Label visible on the guidance bracket intended for wire localization.

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Labelled part	Information on label	Comment
Side cabinet air L30 assembly	SECTRA Sectra MicroDose Mammography Side Cabinet Air Asm Part no: 1006252 Rev. X Mfg date: 20100616 Serial no: 100110-10	Label visible on the inside of the side cabinet door.
Side cabinet water cooling L30 assembly	SECTRA Sectra MicroDose Mammography Side Cabinet water cooling Asm Part no: 1007288 Rev. X Mfg date: 20100616 Serial no: 100110-10	Label mounted on the inside of the side cabinet door.
Daily quality control phantom	SECTRA Daily Quality Phantom Article number: 1010909 Batch number: 2010-03-02	Label visible on the front side.
Calibration phantom	SECTRA Phantom Stepwedge Article number: 1009703 Batch number: 2010-03-02	Label visible on the front side.
Transport package	SECTRA Sectra MicroDose Mammography **Transport and storage** Temperature: +5° to +30° C -10° to +50° C, less than 1 day Humidity: 10% to 75% (non condensing) 95% max, less than 2 weeks **Made in Sweden**	Several identical labels visible outside each of the transport packages.

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SECTRA

Manufacturer

Sectra Imtec AB

Teknikringen 20

SE-583 30 Linköping, Sweden

Phone: +46 13 23 52 00

E-mail: info.imtec@sectra.se

www.sectra.com/medical

For local contact information, visit
www.sectra.com/medical/contact

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